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BARBARA G MCCLUNG
CHIRON CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT R440
P O BOX 8097
EMERYVILLE CA 94662-8097

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☒ is extended to run 4 mos. or continues to run _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 9/17/98 has been considered with the following effect, but it is not deemed to place the application in condition for allowance.

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: _____
   Claims objected to: _____
   Claims rejected: 1-9, 29-36 and 37

   However;

   ☒ Applicant's response has overcome the following rejection(s): Please see attached.

4. ☐ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because _____

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☒ Other Interview Summary attached

(REV. 5-89)

The proposed amendments to claims 1 and 37 would overcome the rejection under 35 USC 103 over Hoskinson et al. and Glass et al. in view of Idson and Remington.

The proposed amendments to claims 1 and 37, along with applicant's arguments, have been considered but not found persuasive to overcome rejection under 35 USC 103 over Woodard et al. in view of Silvestri et al., references of record, for reasons discussed below.

Applicant has asserted that a prior art reference must be considered in its entirety, that there must be some objective reason to combine references, that Woodard teaches that stability of an adjuvant does not affect antibody response, that the presence of emulsifiers may be detrimental in an adjuvant, that considerable experimentation is involved in vaccine technology, that there is no teaching that the prior art compositions could be modified to obtain applicant's compositions, and that the prior art does not teach applicant's compositions as claimed, i.e., consisting essentially of a metabolizable oil and an emulsifying agent, with oil droplets having the claimed size properties ("substantially all of which are less than 1 micron in diameter").

Both Woodard et al. and Silvestri et al., considered in their entirety, have been relied upon for their teachings with respect to oil-in-water, O/W, emulsions. Woodard is concerned with O/W adjuvant compositions and differs, if at all, from applicant's compositions by not specifically referring to oil droplets "substantially all of which are less than 1 micron in diameter." Woodard teaches that it is desirable for adjuvant compositions to be stable and teaches that small droplet size is correlated with stability. Silvestri teaches the desirability of submicron O/W emulsions as well as methods for obtaining them, and is relied upon for those teachings. Woodard and Silvestri are properly combined because they both teach the desirability of making small oil droplets in O/W emulsions, intended for use in antigen or other pharmaceutical compositions, because small, i.e., submicron, droplets result in a more stable emulsion. With respect to applicant's statement that Woodard teaches that stability of an adjuvant does not affect antibody response, the fact that applicant has recognized another advantage (antibody response) which would flow naturally from following the suggestion of the prior art (stability) cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). While applicant has not pointed out which portion of the cited references is relied upon for the assertion that the presence of emulsifiers may be detrimental in an adjuvant, it is noted that Woodard, at page 140, second column, states that "Addition of Tween 80 to the aqueous phase was detrimental to stability and to antibody response"; however, it is apparent that when the quoted statement is taken in the proper context of the reference as a whole, Woodard (see page 138, first column "Emulsions," e.g.) teaches making stable emulsions by first adding surfactant to metabolizable oil and then adding aqueous phase and indicates that surfactant should not be added to the aqueous phase.

Thus Woodard clearly teaches one not to add emulsifiers to the aqueous phase in such a way as to be detrimental to either stability or antibody response. While some experimentation may be required in order make a stable O/W emulsion, both Woodard and Silvestri clearly demonstrate a reasonable expectation for success in doing so, since Woodard and Silvestri exemplify the existence of stable emulsions consisting essentially of a metabolizable oil and an emulsifying agent, with oil droplets having the claimed size properties.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Donna Wortman, Art Unit 1643 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1643 FAX telephone number is (703) 305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday, or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Donna C. Wortman, Ph.D.
Patent Examiner

October 14, 1998